IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **ETHICON WAVE 4 CASES LISTED IN PLAINTIFFS' EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF STEVEN GOLDWASSER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") respectfully submit this Memorandum in Opposition to Plaintiffs' Motion to Exclude Expert Opinion Testimony of Steven Goldwasser, M.D. ("Dr. Goldwasser"). (Pls.' Motion [ECF No. 3677]; Exs. A-C [ECF Nos. 3677-1, 3677-2, 3677-3]; Memorandum [ECF No. 3678].)

INTRODUCTION

Plaintiffs seek to bar the testimony of Dr. Goldwasser, who Ethicon offers as a general expert on the design, safety, and efficacy of Prolift. Plaintiffs support their motion by mischaracterizing the scope and basis for Dr. Goldwasser's opinions – incorrectly claiming he provides opinions about FDA regulations, biomechanical engineering, histopathology, or epidemiology. Contrary to Plaintiffs' framing of these opinions, Dr. Goldwasser properly combines his experience as a surgeon, teacher, and inventor and his review of the medical literature – including Level 1 studies – to not only identify the commonly known risks but to opine on whether the Prolift IFU discloses those enumerated risks from a clinical perspective.

Likewise, Dr. Goldwasser's experience and review of the literature qualifies him to call into question the scientific basis for Plaintiffs' assertions that Ethicon's mesh devices' material properties, including degradation, have negative clinical impact on patients. Ultimately, his opinions would be very instructive to the jury and should be admitted at trial.

DR. GOLDWASSER'S BASES FOR HIS EXPERT OPINION

Dr. Goldwasser is board-certified in obstetrics, gynecology, and female pelvic medicine and reconstructive surgery. (Pls.' Ex. B (Goldwasser Report) at 1.) He completed his residency in obstetrics and gynecology and is fellowship trained in female pelvic medicine and reconstructive surgery. (*Id.* 1-2.) He started the division of Urogynecology at the University of Florida and continues to teach there as a clinical instructor. (*Id.* at 2.) Dr. Goldwasser has been trained in a large variety of female pelvic medicine and reconstructive treatment "including vaginal, abdominal, laparoscopic, robotic, and non-surgical approaches for treating pelvic organ prolapse and urinary incontinence." (*Id.* at 2.) During his training and career, Dr. Goldwasser has designed and implemented various prolapse repair techniques including native tissue, biologic graft, and synthetic graft materials. (*Id.* at 2.) These experiences led to Dr. Goldwasser co-inventing EXAIR, a novel polypropylene mesh graft for the treatment of vaginal prolapse. (*Id.* at 3.)

Thus far in his surgical career, Dr. Goldwasser has performed "well over 1000 surgical procedures" to treat pelvic organ prolapse, and has used synthetic mesh in over 500 procedures. (*Id.* at 3.) He performed about 300 Prolift procedures. (*Id.*) In addition, he has performed over 1000 procedures to treat stress urinary incontinence and used polypropylene mesh in the majority of those cases. (*Id.*) If complications arise, Dr. Goldwasser has experience treating and managing those complications. (Pls.' Ex. C (Goldwasser Dep.) 50:11-14; Pl.s' Ex. B

(Goldwasser Report) at 4.) Moreover, Plaintiffs' counsel himself acknowledged that Dr. Goldwasser is a "great surgeon," a busy surgeon, and one with high rates of success:

> Q. [Plaintiffs' Counsel] And you would agree that higher – doctors that do more frequent surgery have -- probably have higher success rates, right?
> . . .
> A. Correct.
> Q The literature shows that, right?
> A. Correct.
> Q. **And you're a fairly busy surgeon doing these surgeries, right**?
> A. Correct.
> Q. So we would expect your surgery failure rates to be pretty good, right?
> . . .
> A. Failure rates to be pretty low, you mean?
> Q. **I'm sorry, your success rates are going to be pretty high, right**?
> . . .
> A. I'd hope.
> Q Right, because you're -- I mean, part of the reason -- I've seen documents, **you're a great surgeon**, but you're also a busy surgeon, so you have lots of experience, right?
> A. Correct.

(Pls.' Ex. C (Goldwasser Dep.) 33:14-34:11 (emphasis added).)

Dr. Goldwasser's report combines this extensive clinical experience with a reliance upon a large pool of scientific literature and studies as well as the evaluation of many physicians and medical organizations to form opinions to a reasonable degree of medical certainty. (Pls.' Ex. B (Goldwasser Report) at 1.) The materials Dr. Goldwasser cites include Level 1 evidence and the official statements of medical societies. In addition to the materials directly cited in his report, Dr. Goldwasser also reviewed extensive amounts of medical literature identified on his reliance list. (*See generally* Ex. A, Goldwasser, Supplemental General Reliance List.) In short, Dr. Goldwasser's opinion merges his extensive surgical experience with an exhaustive wide-ranging review of the medical literature.

LEGAL STANDARD

Ethicon incorporates by reference the standard of review of *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *1-3 (S.D. W. Va. July 8, 2014).

ARGUMENT

I. Dr. Goldwasser is qualified to opine about the completeness and accuracy of Prolift's warnings from a clinical perspective.

Contrary to what Plaintiffs suggest, Dr. Goldwasser does not offer opinions that Prolift's labeling is "adequate" from a regulatory perspective. Dr. Goldwasser seeks to testify about the completeness and accuracy of the warnings from his clinical perspective. As this Court has previously recognized, "doctors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09–md–02100, 2011 WL 6301625, at *11 (S.D.Ill.Dec.16, 2011)). Moreover, the governing legal standard underlying Plaintiffs' claims *require* the identification of those risks that are outside the scope of a device manufacturer's duty to warn because they are commonly known to surgeons who use the device at issue. It is this testimony that Dr. Goldwasser is uniquely qualified to provide.

In medical device product liability cases, there is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community."). In fact, the FDA device regulation explicitly noted by Dr. Goldwasser says that information may be omitted from labeling:

> if, but only if, the article is a device for which directions, **hazards**, warnings and other information are commonly known to practitioners licensed by law to use the device.

21 C.F.R. §801.10(c) (emphasis added); *see also Wright ex rel. Trust Co. of Kansas v. Abbot Laboratories, Inc.*, 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd.*, 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine). The Prolift IFUs restrict the class of surgeons who may use Prolift:

WARNINGS AND PRECAUTIONS

- Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems.

(Ex. B, Prolift IFU (English excerpts), ver. B, ETH.MESH.02341527.) Accordingly, plaintiffs' failure to warn claim depends on what "hazards" were "commonly" known to surgeons familiar with pelvic floor repair as well as non-absorbable meshes.

This Court has made clear that a physician can draw upon his clinical experience and review of relevant literature to give opinions on a product's safety and efficacy. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products). A physician is qualified to make a comparison between "the risks he perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Winebarger*, 2015 WL 1887222, at *15 (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues). Moreover, a physician is qualified to testify about the completeness of IFUs from a clinical perspective, despite lack of familiarity with FDA regulations and requirements for warnings, or prior experience drafting IFUs. *Id.* at *6-7, 15 (finding

Dr. Galloway qualified to provide opinion on IFUs based on clinical experience despite lack of familiarity with FDA rules or regulations for warnings).

Akin to Drs. Shull and Galloway in *Winebarger*, it is proper for Dr. Goldwasser to use his clinical experience and examination of a large pool of scientific literature to identify the risks that are commonly known to pelvic floor surgeons and give an opinion about whether risks allegedly omitted from the IFU were nonetheless commonly understood as existing risks from *a clinical perspective*:

> As I have already noted above, all pelvic floor surgical procedures have certain commonly known risks. And the risks associated with the Prolift procedure are almost all common to any pelvic floor surgery regardless whether mesh is utilized. Weber AM, Walters MD, Anterior vaginal prolapse: review of anatomy and techniques of surgical repair. Obstet Gynecol. 1997;89:311–318. These risks have been discussed in medical literature discussing pelvic floor surgeries for decades. It is commonly known that any surgery for pelvic organ prolapse can potentially cause complications such as pelvic pain, nerve/vessel injury, scarring, wound complications, bleeding, damage to surrounding organs, voiding problems/retention, dyspareunia, de novo or worsened incontinence, and the need for re-operation due to complications. Surgeons also commonly know that these complications can be mild, moderate, or severe, and temporary or long-term.

(Pls.' Ex. B (Goldwasser Report) 31.) This opinion is particularly appropriate given that Dr. Goldwasser uses his knowledge and experience as an instructor to train young doctors in their residency. It is a far cry from Plaintiffs' argument that Dr. Goldwasser has opined on the adequacy of the Prolift IFU's compliance with regulatory requirements and medical device industry practices. Rather than substantively arguing that Dr. Goldwasser's clinical opinion is inadmissible, they have merely attempted to recast Dr. Goldwasser's opinion into something it is not.

Nevertheless, Plaintiffs may wrongly argue for the first time on reply that the above opinion is precluded by this Court's rulings in *Tyree* and *Bellew*. In those cases, the Court excluded testimony from defense experts who offered opinions that the warnings were adequate

merely because they included risks that the experts observed in their own practices. *See Tyree*, 54 F. Supp. 3d at 584 (S.D.W. Va. 2014); *Bellew v. Ethicon*, Inc., No. 2:13-cv-22473, Dkt. 265 at 33 (S.D.W. Va. Nov. 20, 2014). But, as is made clear above, Dr. Goldwasser's testimony rests not only his own practice but on his historical review of the medical literature as well as his own experience in teaching medical professionals and the statement of the professionals themselves through their professional associations. This makes him well qualified to testify as to what risks are associated with mesh implants, and whether those risks are disclosed in the IFU or are otherwise "commonly known" to those surgeons. Notably, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Goldwasser's conclusion goes to weight, not admissibility and can be addressed on cross-examination. *Tyree*, 54 F. Supp. 3d at 532.

II. Dr. Goldwasser is well-qualified to offer his opinions on degradation and supports them with a reliable methodology.

Dr. Goldwasser opined that "my experience and analysis of the data, including the studies cited in my report, supports my opinion that Ethicon's polypropylene mesh does not degrade in vivo, or if it does, that such degradation does not have any clinically significant effect." (Pls.' Ex. B (Goldwasser Report) at 28-29.) Plaintiffs argue that Dr. Goldwasser offers no reliable methodology for his degradation opinion, that his report was incorrect to say that no evidence exists showing degradation, and that he provided no explanation for a single article purporting to show the clinical significance of degradation.

Dr. Goldwasser has demonstrated the reliability of his methodology. In *Mathison v. Boston Scientific Corporation*, this Court found that a board-certified urologist, Dr. Lonny S.

Green, who had conducted nearly 3,000 sling procedures and practiced for twenty years was qualified to opine that the mesh product does not shrink, contract, degrade, or cause systemic infections. No. 2:13-CV-05851, 2015 WL 2124991, at *28 (S.D. W. Va. May 6, 2015). The Court further found that the doctor's clinical experience and review of scientific literature were sufficiently reliable bases in forming the opinion. *Id.* at *28-29. Like Dr. Green, Dr. Goldwasser has sufficient familiarity and experience with pelvic organ prolapse procedures, transvaginal mesh generally, and the Prolift in particular to provide reliable opinions on whether they shrink, contract, or degrade. Dr. Goldwasser has implanted over a thousand mesh devices (including hundreds of Prolifts), and when mesh complications arise, Dr. Goldwasser treats and manages those complications. (Pls.' Ex. C (Goldwasser Dep.) 50:11-14; Pl.s' Ex. B (Goldwasser Report) at 3-4 (stating that Goldwasser's practice also involves "treating and managing complications associated with native tissue repairs, **transvaginal mesh**, and sacralcolpopexies." (emphasis added).) At his deposition, Dr. Goldwasser entertained a lengthy discussion about what he has seen and not seen during his management and treatment of these complications. (*See e.g.*, Pl.s' Ex. C (Goldwasser Dep.) 64:10-16 ("Q. And so what complications have you seen after a transvaginal mesh-based repair for prolapse? A. Erosions, or exposure in the vaginal canal. I have seen failures. I've seen overcorrections. I've seen irritative voiding symptoms. I've seen overactive bladder symptoms in general."), 67:6-76:3 (discussing his observations regarding tensioning, bunching, roping, curling, pore size, scar formation).) This is consistent with prior rulings in this MDL, where this Court has allowed urologists, gynecologists, and urogynecologists with extensive experience in treating pelvic organ prolapse, including the mesh devices at issue, to testify that they have not experienced certain alleged physical properties (such as degradation) in the mesh devices at issue. *See, e.g., Trevino v. Boston Scientific Corp.*,

2016 WL 2939521, at *45 (S.D. W. Va. May 19, 2016) (finding that a practicing urogynecologist who is board-certified in obstetrics and gynecology and had extensive experience in treating stress urinary incontinence and pelvic organ placing, including Prefyx and Uphold mesh slings, was "qualified him to testify that he has not experienced certain alleged physical properties in the defendant's Uphold and Prefyx devices."); *see also id.* at *5 (finding that urologist Niall Galloway's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage and contraction"); *id.* at *33 (allowing testimony of defense expert Patrick Culligan, M.D.); Huskey, 29 F. Supp. 3d at 706-07, 735 (rejecting similar challenges to plaintiff expert Bruce Rosenzweig, M.D., and defense expert urogynecologist Harry Johnson, M.D.); *Tyree*, 54 F. Supp. 3d at 550, 585 (rejecting similar challenge of plaintiff expert Donald Ostergard, M.D. and defense expert Lonny Green, M.D.); *Jones v. Bard, Inc.*, No. 2:11–cv–00114, [Doc. 391], at 6–9.

Regarding the purported inaccuracy in his report, Dr. Goldwasser never stated his ultimate opinion was wrong. He did clarify at his deposition that "[t]here are articles on both sides of the argument, one saying [mesh] degrades, another says it doesn't." (Pls.' Ex. C (Goldwasser Dep. 194:21-23.) Plaintiffs, however, failed to note that Dr. Goldwasser accounted for this literature in his report (Pls.' Ex. B (Goldwasser Report) at 28) (addressing contentions of "cracked surfaces" of the mesh), his opinion (*id.* at 29 (stating that "mesh does not degrade in vivo, or if it does . . ."), and his deposition testimony. (Pls.' Ex. C (Goldwasser Dep.) 195:5-6 (plaintiffs' experts "think that they are showing degradation").)

Finally, when Plaintiffs asked about a single article purporting to show the clinical significant of degradation, Dr. Goldwasser responded by referring to the articles showing *there was no* clinical significance:

> Q. And so my question is, what -- what reason do you have to discount the findings of this article that was -- you reviewed in preparation for your report?
> . . .
> A. No more than the ones that support that there's no problem.

(Pls.' Ex. C (Goldwasser Dep.) 202:6-12.) Plaintiffs' counsel, however, chose not to probe further on this point. Dr. Goldwasser further added that he had reviewed articles on both sides of the degradation issue and had considered them in coming to his degradation opinion. (*Id.* at 205:12-206:6.)

In short, Plaintiffs have only provided an outline for cross-examination, not an argument for inadmissibility under *Daubert*. Plaintiffs' counsel were free to, and did, cross-examine Dr. Goldwasser on these points. But these attacks only go the weight of Dr. Goldwasser's testimony before the jury, not its admissibility. *See, e.g.*, *Trevino*, 2016 WL 2939521, at *40 ("If there are certain device-specific publications that [Plaintiffs claim that Dr. Flynn] failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination."); *Huskey*, 29 F. Supp. 3d at 735 ("Dr. Johnson's failure to review particular documents goes to the weight of his opinion, not its admissibility.").

III. Dr. Goldwasser's testimony regarding risks commonly known to pelvic floor surgeons is relevant, reliable and is not inadmissible "State-of-Mind" testimony.

Plaintiffs mischaracterize Dr. Goldwasser's report and testimony by focusing on one sentence at the end of Dr. Goldwasser's report. (Pls.' Ex. B (Goldwasser Report) 30.) In over half a dozen instances, Dr. Goldwasser makes clear that he is opining on what is "commonly known" among pelvic floor surgeons. Dr. Goldwasser is not opining about any particular surgeon's actually knowledge or state of mind, but rather what risks were generally known by the surgical community. (*Id.* at 30-32.) As stated above in Point I, his extensive experience as a surgeon, teacher, and inventor (combined with his review of the literature) qualifies him to do this. Plaintiffs' Motion on this point should be rejected for substantially the same reasons

outlined in Point I.

IV. Dr. Goldwasser's testimony based on his personal experience is well supported.

Plaintiffs also seek to preserve a right to supplement this motion based on their request for disclosure of a patient vaginal prolapse database that Dr. Goldwasser shares with a urologist colleague at the University of Florida. (Pls.' Ex. B (Goldwasser Report) at 3.) Even without the existence of a database, however, Dr. Goldwasser's personal experience as a surgeon, teacher, and inventor, coupled with his extensive review of the medical literature, is sufficient to support his opinions. As this Court has recognized, *Daubert* does not require independent verification of "every single clinical experience he had over the course of his career," because otherwise, "the court would never make it past pre-trial motions." *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Doc. 265, p. 40 (S.D. W. Va. Nov. 20, 2014); *see also Winebarger*, 2015 WL 1887222, at *34 (finding that expert's lack of "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable and that "such detail is not required under Daubert to opine as to 'large-scale safety and efficacy of the Uphold device'"); *Trevino*, 2016 WL 2939521, at *33 (same). Accordingly, Plaintiffs' request to limit Dr. Goldwasser's testimony on this basis is misplaced.[1]

CONCLUSION

For the foregoing reasons, the Court should DENY Plaintiffs' motion to exclude the expert testimony of Steven Goldwasser, M.D., in its entirety.

[1] At Dr. Goldwasser's deposition, Ethicon provided Plaintiffs with published abstracts regarding data included in this database (Pls. Ex. C (Goldwasser Dep.) 9:11-17), but Plaintiffs' counsel chose to neither mark them as exhibits nor ask questions about them. Ethicon has objected to the disclosure of the database itself, both before and during the deposition. (Pls. Ex. C (Goldwasser Dep.) 80:7-9.)

Respectfully submitted,

April 27, 2017

/s/ Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

/s/ Kelly Crawford
Kelly Crawford
Riker Danzig Scherer Hyland &
Perretti, LLP
Headquarters Plaza
One Speedwell Avenue
Morristown, NJ 07962-1981
(973) 451-8417
kcrawford@riker.com

COUNSEL FOR DEFENDANTS
ETHICON, INC. AND JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I certify that on April 27, 2017, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Kelly Crawford
Kelly Crawford

36338234v1